

E3 cont molecule, which 8F4 inhibitory molecule is a monoclonal antibody that recognizes a human 8F4 polypeptide, wherein said 8F4 polypeptide:

- a) is an inducible T cell costimulatory molecule;
- b) occurs on two-signal-activated human T lymphocytes;
- c) exhibits a molecular weight of about 55 to 60 kilodaltons as determined by non-reducing sodium dodecyl sulphate polyacrylamide gel electrophoresis (SDS-PAGE);
- d) is a dimer of two peptide chains exhibiting molecular weights of about 27 kilodaltons and 29 kilodaltons, as measured by reducing SDS-PAGE; and
- e) is recognized by the antibody deposited with the DSMZ and assigned accession no. DSM ACC2539,

in an amount sufficient to inhibit rejection of an organ transplant.

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#### REMARKS

Claims 21, 25-28, 30 and 32-35 were under consideration in the present application.

The specification has been amended to include information regarding the deposit of the 8F4 antibody. No new matter is introduced by virtue of this amendment.

Claim 21 has been amended to correct an informality. Claims 21 and 30 have also been amended to more particularly point out and distinctly claim that which Applicant regards as the invention. Support for this amendment can be found, *inter alia*, in Examples 2 and 8 of the specification, at pages 12 and 18, respectively. No new matter is added.

#### CLAIM OBJECTION

The Examiner objects to claim 21 because of an informality. In particular, the last line recites "modulated" rather than "inhibited."

Applicant has amended claim 21 by replacing the term "modulated" with "inhibited." Accordingly, Applicant requests that the objection to claim 21 be withdrawn.

#### **THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH SHOULD BE WITHDRAWN**

Claims 21, 25-28, 30 and 32-35 are rejected under 35 U.S.C. § 112, second paragraph, allegedly as indefinite because the term "8F4 polypeptide" is not distinctly claimed. The Examiner further states that the rejection would be overcome by recitation of a

sequence identifier of the amino acid sequence of the 8F4 polypeptide or by recitation of the 8F4 polypeptide's ability to be recognized by a deposited antibody.

Without agreeing with the Examiner in any way, and merely to expedite prosecution, Applicant has amended independent claims 21 and 30 (and therefore claims 25-28 and 32-35 dependent thereon) to recite that the 8F4 polypeptide is recognized by the antibody deposited with the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH and assigned accession no. DSM ACC2539. Further, Applicant submits herewith as Exhibit D a copy of a Declaration of Applicant Regarding Permanence and Availability of Deposited Microorganisms ("Declaration") and attached Exhibit 1, a copy of hybridoma deposit receipt, originally filed in connection with parent application no. 09/509,283 on August 19, 2002. The Applicant, being in a position to verify the identity of the deposited hybridoma, states in the Declaration that the hybridoma deposited under the conditions of the Budapest Treaty is the hybridoma specifically identified in the application as filed.

In view of the foregoing amendments, remarks, and accompanying Declaration, Applicant submits that the rejections under 35 U.S.C. § 112, second paragraph, have obviated and should be withdrawn.

**THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH,  
FOR LACK OF ENABLEMENT SHOULD BE WITHDRAWN**

Claims 21, 25-28, 30 and 32-35 are rejected under 35 U.S.C. § 112, first paragraph, allegedly as lacking enablement. In particular, the Examiner alleges that the instant claims encompass the use of antibodies to a "genus" of 8F4 polypeptides that is beyond the teachings of the specification. The Examiner further states that the rejection would be overcome by recitation of a sequence identifier of the amino acid sequence of the 8F4 polypeptide or by recitation of the 8F4 polypeptide's ability to be recognized by a deposited antibody.

Without agreeing with the Examiner in any way, and merely to expedite prosecution, Applicant has amended independent claims 21 and 30 (and therefore claims 25-28 and 32-35 dependent thereon) to recite that the 8F4 polypeptide is recognized by the antibody deposited with the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH and assigned accession no. DSM ACC2539. Further, as discussed above, Applicant submits herewith as Exhibit D a copy of a Declaration of Applicant Regarding Permanence and Availability of Deposited Microorganisms ("Declaration") and attached Exhibit 1, a copy of hybridoma deposit receipt, originally filed in connection with parent application no.

09/509,283 on August 19, 2002. As also discussed above, the Applicant, being in a position to verify the identity of the deposited hybridoma, states in the Declaration that the hybridoma deposited under the conditions of the Budapest Treaty is the hybridoma specifically identified in the application as filed.

In view of the foregoing amendments, remarks, and accompanying Declaration, Applicant submits that the rejections under 35 U.S.C. § 112, first paragraph, for lack of enablement, have obviated and should be withdrawn.

### CONCLUSION

Applicant respectfully requests entry of the foregoing amendments and consideration of the foregoing remarks. Applicant believes the claims to be in condition for allowance. An allowance is earnestly requested.

Respectfully submitted,

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Enclosures